Q2 cont

2. (Amended) A composition of claim 1, wherein the drug release controlling component allows levosimendan to be released substantially completely before the composition reaches the large intestine of the host to which the composition is to be administered.

3. (Amended) A composition of claim 1, [or 2] wherein the drug release controlling component is hydrophilic gel forming polymer or a vegetable fat or oil or a fatty acid ester.

4. (Amended) A controlled release composition for oral administration comprising a) a therapeutically effective amount of levosimendan and b) a drug release controlling component for providing the release of levosimendan over an extended period of time, wherein the total in vitro dissolution time of the composition, determined according to the USP XXII basket assembly method in phosphate buffer pH 5.8, ranges from about 1 to about 4 [is substantially between 1 and 4] hours for at least 90 percent [per cent] of the content of levosimendan.

7. (Amended) A composition of claim 5, [or 6] wherein the rapid release portion comprises levosimendan and microcrystalline cellulose.

8. (Amended) A composition of claim 6, [or 7] wherein the release controlling hydrophilic gel forming polymer is hydroxypropylmethyl cellulose, alginic acid or a mixture thereof.

9. (Amended) A composition of claim 5, [any of claims 5 - 8] wherein about 25 to about [-] 75% by [, preferably about 30 - 70%, more preferably about 40 - 60% per] weight of levosimendan [the drug] is in the controlled release portion.

10. (Amended) A composition of claim 6, [any of claims 5 - 9] wherein the amount of the hydrophilic gel forming polymer is about 20 to about [-] 80% by [, preferably about 30 - 70%, per] weight of the composition.

Q3

--11. A composition of claim 1, wherein the drug release controlling component provides for a steady-state plasma level for the levosimendan metabolite of less than 10 ng/ml.

A3 cont.

12. A composition of claim 5, wherein about 30 to about 70% by weight of levosimendan is in the controlled release portion.

13. A composition of claim 5, wherein about 40 to about 60% by weight of levosimendan is in the controlled release portion.

14. A composition of claim 6, wherein the amount of the hydrophilic gel forming polymer is about 30 to about 70% by weight of the composition.

15. A method for the treatment of congestive heart failure, which comprises administering to a host in need of the treatment a composition of claim 1.

16. A method for the treatment of congestive heart failure, which comprises administering to a host in need of the treatment a composition of claim 4.

17. A method for the treatment of congestive heart failure, which comprises administering to a host in need of the treatment a composition of claim 5.--

Remarks

Claims 1-17 are pending in this application. Support for new claims 11-14 appears in original claims 1, 9 and 10. Support for new claims 15-17 appears on page 1, lines 3-7 of the specification.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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By: _____
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